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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,078	07/19/2004	Patrick Wuthrich	SERVIER 426 PCT	2097

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EXAMINER

HAWES, PILI ASABI

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/502,078

Applicant(s)

WUTHRICH ET AL.

Examiner

Pili A. Hawes

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 12-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

3.00

DETAILED ACTION

Summary

Claims 1-11 have been cancelled. New claims 12-25 have been added. Claims 12-25 are pending in this action. Claims 12-25 are rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-17, 19, 20, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Rault et al. US 5672356.

Rault discloses a rapid release (col. 1, line 10) tablet composition comprising piribedil, maize starch, and lactose (col. 4, lines 5-8). Example 2 discloses the composition contains 320 grams piribedil, 278 grams lactose and 80 grams starch. Thus the composition contains 47% piribedil and 52% lactose and starch, which anticipates the amounts claimed by applicant. The powder obtained is dried (col. 2, lines 60-62) before it is compressed (col. 3, line 4). The reference also teaches the use of lubricants, disintegrants, diluents, and binders (col. 6, lines 45-48).

Claims 12 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Dumont et al. US 4112093.

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Dumont discloses a method of treating Parkinson disease in a warm-blooded mammal with tablets of piribedil (col. 1, lines 19-21). The tablets contain lactose and starch (col. 1, line 64).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khankari et al. US 6024981.

Khankari discloses a hard compressed, rapidly dissolving tablet for oral dosage, comprising particles containing active ingredients, and a matrix including non-direct compression fillers and a wicking agents (col. 21, lines 45-50). The tablet having hardness between 15-50 Newtons (col. 22, line 4). The tablet also has the ability to dissolve in a patients mouth in less than about 60 seconds (col. 22, line 8). The

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reference lists lactose as an example of a non-direct compression sugar that can be used in this tablet formulation (col. 9, line 66). Starches and modified starches are listed as exemplary wicking agents (col. 13, lines 54-55). Citric acid is used in the formulation (col. 17, line 28). Lubricants and glidants are employed in the formulation as well (col. 17, lines 1-10). The dosage form is suitable for a variety of pharmaceutical ingredients such as sedatives, antihyperactives, antihypertensives, tranquilizers, decongestants, beta blockers, and their combination (col. 21, lines 1-8).

It would be obvious to one of ordinary skill in the art to add the active ingredient piribedil into the formulation disclosed by Khankari because the dosage form is able to rapidly dissolve in less than 90 seconds with a minimal amount of grit or other organoleptically unpleasant species. One of ordinary skill in the art would be motivated to make such tablet because some patients are unable or unwilling to swallow a tablet or a capsule so a fast dissolving dosage form would be more favorable to deliver the beneficial agent. One of ordinary skill in the art would have a reasonable expectation of success in making a rapidly dissolving oral dosage form with piribedil, because Khankari teaches the dosage form works with a variety of pharmaceutical agents from various therapeutic classes.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6770368 B2 (Luhn, discloses granules based on starch and lactose and making tablets)

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US 2004/0058896 A1 (Dietrich et al., discloses rapidly disintegrating tablet formulations comprising lactose, starch, and a myriad of active agents)


US 5006345 (Lang, discloses direct tableting procedures with lactose and other another carrier, like starch)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

P.A. Hawes
Examiner-1615


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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